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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, ASTRAZENECA LP,  
KBI-E INC., and POZEN INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES INC. and  
DR. REDDY'S LABORATORIES LTD.,

Defendants.

Case No. 3:13-cv-00091 (JAP)(DEA)

Consolidated for discovery  
purposes with:

Case No. 3:11-cv-02317 (JAP)(DEA)

Case No. 3:11-cv-04275 (JAP)(DEA)

Case No. 3:11-cv-06348 (JAP)(DEA)

**Motion Date: September 3, 2013**

**PLAINTIFFS' OPPOSITION TO DRL'S  
MOTION TO STRIKE PLAINTIFFS' VALIDITY CONTENTIONS**

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## I. INTRODUCTION

DRL premises its Motion to Strike Plaintiffs' Validity Contentions on the assertion that DRL I and DRL II are completely separate cases. Even accepting this premise, DRL's arguments in support of its motion fail. Plaintiffs have affirmatively requested declaratory relief that U.S. Patent No. 6,926,907 (the "'907 patent") is valid; validity is therefore at issue in DRL II regardless of the defenses DRL pursues. Plaintiffs properly-served Validity Contentions put forward evidence in support of their request for declaratory relief, responding to what Plaintiffs reasonably believe are DRL's invalidity arguments. Further, DRL's purported attempt to narrow the issues by not pursuing invalidity as an affirmative defense is inapposite because it does not resolve the live issue between the parties: Plaintiffs still have a pending request for declaratory relief on validity and DRL refuses to unconditionally stipulate to the '907 patent's validity.<sup>1</sup>

If the Court rejects DRL's premise that DRL I and DRL II are completely separate cases, DRL's Motion to Strike should likewise be denied. DRL attempts to exploit the Local Rules outside of the context under which they normally operate, to act as both a sword and a shield by continuing to pursue an invalidity defense "in DRL I" while preventing Plaintiffs from serving Validity Contentions "in DRL II." Further, if Plaintiffs' Motion for Summary Judgment is not granted, invalidity will play a role in both DRL I and DRL II, and DRL's actions to date will have done nothing to narrow the issues between the parties.

Because validity is at issue in DRL II and none of DRL's actions have resolved the issue, Plaintiffs properly served their Validity Contentions in DRL II and ask that this Court deny DRL's Motion to Strike.

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<sup>1</sup> Plaintiffs believe the procedural consequence of DRL's decision not to serve Invalidity Contentions in DRL II is that Plaintiffs' Motion for Summary Judgment that the '907 Patent is Not Invalid should be granted. Dkt. 152. However, this memorandum addresses only the arguments raised in DRL's Motion to Strike Plaintiffs' Invalidity Contentions. Dkt. 167.

## II. STATEMENT OF THE FACTS

DRL notified Plaintiffs that it filed an Abbreviated New Drug Application (“ANDA”) relating to Plaintiffs’ VIMOVO® drug product on March 11, 2011. In response, Plaintiffs filed a patent infringement lawsuit against DRL (“DRL I”) asserting, among other things, that DRL infringed the ’907 patent. Dkt. 1 at 7-9. DRL asserted in its Answer and Counterclaims that the ’907 patent is invalid (Dkt. 28 at 5 and 9) and served Invalidity Contentions. Plaintiffs served Validity Contentions and later sought leave to amend their Contentions. Dkt. 98. After the issue was fully briefed (Dkts. 98, 116, 125, 129), the Court denied Plaintiffs’ request. Dkt. 134.

Separately, DRL notified Plaintiffs that it had filed a second ANDA relating to Plaintiffs’ VIMOVO® drug product on November 20, 2012. In its second ANDA, DRL certified to the FDA, *inter alia*, that the ’907 patent is invalid. DRL confirmed this certification of invalidity in a Notice Letter sent to Plaintiffs. In that letter, DRL set forth, in detail, the bases for its certification to the FDA that it believed the ’907 patent to be invalid. Plaintiffs responded by filing a second patent infringement lawsuit against DRL (“DRL II”) alleging, among other things, infringement of the ’907 patent and, in response to DRL’s certification, requesting a declaration that the ’907 patent is valid. Civ. Case No. 13-cv-91, Dkt. 1 at 9-11 and 19. In response, DRL again claimed that the ’907 patent is invalid in its Answer. Civ. Case No. 13-cv-91, Dkt. 5 at 9.

On May 9, 2013, the Court held a status conference at which the parties agreed to consolidate DRL II with DRL I for discovery purposes, and both parties agreed to a Scheduling Order providing for, among other things, service of DRL’s Invalidity Contentions and Plaintiffs’ Validity Contentions.<sup>2</sup> See Dkts. 144, 145. Despite agreeing to a schedule for service of

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<sup>2</sup> DRL mischaracterizes Judge Arpert’s entry of a Scheduling Order to “exchange new contentions” as being based upon the difference between the formulation of DRL’s first and

Invalidity and Validity Contentions, DRL did not serve any Invalidity Contentions on May 23, 2013, the date set out in the Order. As validity was still an issue in light of Plaintiffs' request for a declaration of validity and DRL's maintenance of its invalidity defenses, Plaintiffs' served their Validity Contentions on June 13, 2013, the date set out in the Order. Though DRL requested that Plaintiffs withdraw their Contentions, DRL concurrently refused to stipulate to the patent's validity in all pending and future litigation. *See* Dkt. 168, Ex. A and B. The validity of the '907 patent thus remains a matter in dispute between the parties, and therefore, Plaintiffs cannot withdraw their Validity Contentions in DRL II.

DRL's decision to not serve validity contentions in an effort to cut off Plaintiffs' opportunity to amend their invalidity responses in DRL I has triggered an extensive letter-writing campaign and several conferences and motions practice with the Court. In response to DRL's insistence that it was not relying on Contentions served in DRL I and admission that it produced no evidence to contradict validity in DRL II, Plaintiffs filed a Motion for Summary Judgment that the '907 Patent is Not Invalid. Dkt. 152. DRL then wrote Judge Pisano a letter requesting a hearing to discuss the Summary Judgment Motion and Contention issue. Dkt. 158. As a result, Judge Pisano scheduled a Telephone Conference on July 22, 2013, during which Judge Pisano suggested that DRL could moot both issues by agreeing that it would not challenge the validity of the '907 patent in any present or future litigation. Accordingly, Plaintiffs proposed such a stipulation (Dkt. 168, Ex. A), and DRL refused to agree, instead countering with a stipulation limited to *only* DRL II and expressly reserving the right to challenge validity elsewhere, including in DRL I. Dkt. 168, Ex. B.

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second ANDA products. Dkt. 167 at 3. Judge Arpert stated the default, absent objection, is to enter a Scheduling Order calling for both Infringement/Non-Infringement and Invalidity/Validity Contentions. Neither party objected; therefore, the Order calling for both was entered. Dkt. 145.

**III. PLAINTIFFS SERVED VALIDITY CONTENTIONS IN SUPPORT OF THEIR REQUEST FOR DECLARATORY RELIEF THAT THE '907 PATENT IS VALID.**

Plaintiffs' Complaint in DRL II requests declaratory relief affirming the validity of the '907 patent. DRL's strategic decision not to pursue an invalidity defense by not serving Invalidity Contentions in DRL II did nothing to divest the Court of jurisdiction on this issue in DRL II. The bases for the existence of a dispute between Plaintiffs and DRL regarding the validity of the '907 patent have not changed: DRL has not withdrawn its certification to the FDA as to the validity of the '907 patent; DRL has not revised or amended its Notice Letter to Plaintiffs detailing the bases for its certification that the '907 patent is invalid; DRL has not amended or sought to amend its answer in which it affirmatively plead that the '907 patent is invalid; and DRL has not unconditionally stipulated to the '907 patent's validity.

Plaintiffs put forward their Validity Contentions as evidence to support their request for a declaration of validity. That Plaintiffs will benefit from the presumption of validity should not preclude the introduction of supporting evidence for a live issue in the case.

**A. Plaintiffs' Validity Contentions Respond to DRL's Anticipated Invalidity Arguments.**

In its opening brief, DRL asserts "there is no predicate for any [] 'responsive' contentions supporting validity" because "DRL has no contentions challenging validity in DRL II." Dkt. 167 at 1. However, because of the nature of Hatch-Waxman litigation and the unique posture of this case, Plaintiffs were well aware of DRL's invalidity arguments, and Plaintiffs' Validity Contentions respond to those arguments.

**1. The Hatch-Waxman Act Statutorily Requires ANDA Filers to Include the Bases for an Invalidity Certification in Their Notice Letter.**

Based upon the statutory requirements under the Hatch-Waxman Act, DRL revealed its intent to challenge the '907 patent's validity to both the U.S. Food and Drug Administration

(“FDA”) and Plaintiffs before DRL II was ever filed. The Hatch-Waxman Act directs that certain steps must be taken in conjunction with an ANDA. For each patent that will not expire before the ANDA filer’s intended launch, the ANDA filer must certify to the FDA that “in the opinion of the applicant and to the best of his knowledge” the patent is “invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.” 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Following this certification, the ANDA filer must send the patent and New Drug Application (“NDA”) holders a Notice Letter including, among other things, “a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” 21 U.S.C. § 355(j)(2)(B)(iv)(II). The patent and/or NDA holders can then sue for infringement or the ANDA filer can file for a declaratory judgment. *See* 21 U.S.C. § 355(c)(3)(D)(i).

DRL followed these regulatory steps and sent the appropriate certifications to the FDA for its second ANDA product directed to VIMOVO®. DRL also sent Plaintiffs the required corresponding Notice Letter on November 20, 2012, detailing the factual and legal bases for its certifications to the FDA. Numerous bases for invalidity of the ’907 patent were included in the letter.<sup>3</sup> Therefore, before filing suit in DRL II, Plaintiffs were already aware of DRL’s challenges to the ’907 patent’s validity and preemptively requested declaratory relief on the issue.

**2. This Case has a Unique Posture Because Invalidity Contentions Were Previously Served in a Copending Case.**

DRL II arises under unique circumstances: a previously filed case (DRL I) is already pending before the same Judge in the same Court that involves the same patent and the same

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<sup>3</sup> As DRL certified to the FDA that the ’907 patent is invalid, unenforceable and/or not infringed and then in the Notice Letter provided a detailed accounting of the bases for this certification, including a 22 page account of its contention that the ’907 patent is invalid, it is disingenuous for DRL to argue, as it has, that it has not certified to the FDA that the ’907 patent is invalid.



innovator drug. Because of this unusual posture, Plaintiffs are very much aware of DRL's invalidity positions regarding the '907 patent. Therefore, when Plaintiffs chose to put forward evidence to rebut DRL's invalidity defense and support their request for a declaration that the '907 patent is valid, Plaintiffs addressed the bases of invalidity that were raised in both DRL's second Notice Letter and the Invalidity Contentions served in DRL I.

This case is distinguishable from the usual situation in which only one case is pending between the parties. In the latter situation, under the normal operation of the Local Rules, if a party challenging validity does not serve Invalidity Contentions, the party defending validity need not, and has no motivation to, serve Validity Contentions because it is assured the validity of its patent is not contested. *See* Local Patent Rules 3.3/3.6(c) and 3.4A/3.6(i). Indeed, if this were the case here and Plaintiffs were assured that their request for declaratory relief that the '907 patent is valid would be granted or that DRL would not challenge the patent's validity in any litigation, Plaintiffs would not have filed Validity Contentions. However, DRL refuses any such assurance. *See* Dkt. 168, Ex. A (letter from Plaintiffs to DRL proposing a stipulation, in which DRL would have agreed to not challenge the validity of the claims of the '907 patent in any current or future proceeding) and Ex. B (letter from DRL rejecting Plaintiffs' proposed stipulation). Therefore, Plaintiffs served Validity Contentions in DRL II because they had, and continue to have, no assurance that DRL will not challenge the validity of the '907 patent.

**B. DRL's Actions Have Not Narrowed the Issues in DRL II.**

Because DRL refuses to stipulate to the validity of the '907 patent, Plaintiffs' request for declaratory relief on patent validity remains unresolved. Therefore, DRL's decisions to not serve Invalidity Contentions and to not pursue an invalidity defense in DRL II do not impact whether validity is at issue in DRL II.

DRL has repeatedly asserted that it does not challenge the validity of the '907 patent in DRL II. *See e.g.*, Dkt. 147 at 2, Dkt. 164 at 1, Dkt 167 at 4. However, DRL's assertions ring hollow because DRL refuses to fully stipulate to the validity of the '907 patent. At the July 22, 2013 Telephone Conference with Judge Pisano, DRL related its opinion that Plaintiffs' Motion for Summary Judgment (Dkt. 152) should not be entertained by the Court because invalidity is not at issue in DRL II due to DRL's deliberate decision to not serve Invalidity Contentions. *See also*, Dkt. 158. Judge Pisano's response was that DRL could moot the motion if it stipulated to the validity of the '907 patent in all present and future litigations.<sup>4</sup> DRL refused to so stipulate. *See* Dkt. 168, Ex. A and B.

Because of DRL's refusal to stipulate to the validity of the '907 patent, Plaintiffs' request for a declaration that the '907 patent is valid is not resolved and therefore is still at issue in DRL II. Plaintiffs properly served their Validity Contentions in support of their validity position, and DRL's Motion to Strike should be denied.

**IV. IF THE COURT REJECTS DRL'S PREMISE THAT THE CASES ARE COMPLETELY SEPARATE, DRL SHOULD NOT BE PERMITTED TO USE THE LOCAL RULES TO SIMULTANEOUSLY PURSUE AN INVALIDITY ARGUMENT "IN DRL I" AND BLOCK PLAINTIFFS' VALIDITY ARGUMENTS "IN DRL II."**

If the Court declines to adopt DRL's proposition that DRL I and DRL II are completely separate cases, DRL's Motion to Strike should likewise be denied. DRL I and II arose out of DRL's decision to serially file separate ANDAs directed toward VIMOVO®. The cases involve the same parties, the same patent, the same District Court, and the same Judge. The cases have

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<sup>4</sup> As set out in Plaintiffs' Reply in support of their Motion for Summary Judgment (Dkt. 168), such a stipulation would be analogous to a patentee divesting the court of jurisdiction in the typical declaratory judgment context by granting the accused infringer "a covenant not to assert the patent at issue against the putative infringer with respect to any of its past, present, or future acts." *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995) (citing *Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 636-38 (Fed. Cir. 1991)).

further been consolidated for discovery purposes and will likely be tried together. Because of the unique posture of the two cases, DRL attempts to leverage the Local Rules to prevent Plaintiffs from serving Validity Contentions in DRL II, while preserving and continuing to pursue its invalidity arguments in DRL I. Regardless of whether DRL served Invalidity Contentions in DRL II, invalidity *is* at issue; if the patent is held invalid in DRL I, DRL II stands to benefit regardless of whether DRL separately challenges invalidity in DRL II. *See Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (overruling prior precedent “to the extent it forecloses a plea of estoppel by one facing a charge of infringement of a patent that has once been declared invalid.”); *Manildra Mill. Corp. v. Ogilvie Mills, Inc.*, 76 F.3d 1178, 1183 (Fed. Cir. 1996) (“A judicial declaration that one is free from another's right to exclude alters the legal relationship between the parties. The patentee no longer can enforce his patent against the would-be infringer litigant, or any other would-be infringer.”) (citing *Blonder-Tongue*, 402 U.S. at 349-50).

Further, DRL’s insistence that it is not asserting an invalidity defense in DRL II does not narrow the issues to be investigated, litigated or adjudicated. All practical considerations—DRL’s actions, the interests of all parties involved, and judicial economy—indicate DRL I and DRL II will be tried together. At this single trial, DRL’s line drawing between the two cases will have no practical impact on the number of issues to be resolved. Though DRL argues “there is no certainty that DRL I and DRL II will be tried together,” (Dkt. 167 at 8) it is contrary to common sense to believe that consolidated cases brought by the same Plaintiffs, against the same defendant, involving the same patent, before the same Judge, which have already been consolidated for discovery purposes will be tried separately. In fact, a consolidated case benefits DRL by minimizing costs associated with going to trial and any potential delay on DRL’s

ANDA products' respective market entries. DRL has already expressed an interest in proceeding to trial as quickly as possible to avoid such an outcome. *See* Dkt. 77, DRL Opp'n to Anchen Motion to Consolidate at 8 ("DRL's ability to receive and make full use of its exclusivity requires DRL to complete this case quickly[.]"). Further, DRL previously agreed to a schedule that would try both cases together and has expressed no interest in trying the cases separately. Finally, patent cases require lengthy time commitments from the Court, and a consolidated trial will conserve judicial resources. Thus, DRL's alleged attempt to "narrow" the issues and "not litigate" invalidity in DRL II will have no practical impact on DRL's preparation for trial,<sup>5</sup> the trial itself, or the number of issues adjudicated.

If the Court decides that DRL I and DRL II are not completely separate cases, DRL's distinction between its invalidity defense in DRL I and its invalidity defense, or lack thereof, in DRL II should not permit DRL to hide behind the usual operation of the Local Rules and prevent Plaintiffs from serving their Validity Contentions. The distinction is inapposite because an invalidity holding in either case will affect both. The facts remain: DRL does challenge the '907 patent's validity, DRL served Invalidity Contentions in DRL I, DRL chose to file a second ANDA that resulted in DRL II, and DRL I's holding with respect to validity will impact DRL II. Therefore, Plaintiffs should be allowed to present their validity arguments in DRL II.

## **V. CONCLUSION**

For the foregoing reasons, Plaintiffs respectfully request that the Court deny DRL's Motion to Strike Plaintiffs' Validity Contentions.

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<sup>5</sup> Plaintiffs note that DRL has completed minimal discovery on invalidity to date. Not litigating invalidity "in DRL II" will have minimal impact, if any, on the tasks that remain to be completed by DRL before the close of discovery.

Dated: August 20, 2013

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**CERTIFICATE OF SERVICE**

I hereby certify that on August 20, 2013, I caused a true and correct copy of PLAINTIFFS' OPPOSITION TO DRL'S MOTION TO STRIKE PLAINTIFFS' VALIDITY CONTENTIONS to be served on the below listed counsel of record via email:

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